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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------------|------------------|
| 10/660,997      | 09/12/2003  | David J. Ecker       | IBIS0063-100/DIBIS-0002US | 7707             |

58057 7590 05/26/2006

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/660,997

Applicant(s)

ECKER ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-19 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 and 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/24/03; 12/24/03; 5/14/04</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II in the reply filed on March 29, 2006 is acknowledged.

### ***Priority***

2. It is noted that the parent application 09/798,007, does not teach VNTR. A word search of VNTR or variable with number did not yield any results in 09/798,007. Therefore, claims 16 and 33 do not receive priority to that application.

### ***Claim Rejections - 35 USC § 112***

3. Claims 14-19 and 29-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, the word "thereby" is repeated in the second to last line. Correction is required.

Claim 16 is indefinite because it involves the use of VNTR sequences for genotyping, but depends from claim 14, which uses rRNA sequences for genotyping. As the specification shows on page 38, in example 15, VNTR analysis involves loci that are not the ribosomal RNA sequences. Thus, it is indefinite what is being analyzed in claim 16 since it cannot be the rRNA from claim 14, but no other target is provided.

Claims 17-19 are indefinite for essentially the same reason as claim 16. These claims are even further from the rRNA sequences used in claim 14, with claim 17 using a "pathogenicity factor", claim 18 limiting that factor to a "pathogenicity island", a

“virulence marker” or a “toxin compound”, and claim 19 referring to a toxin gene inserted by genetic engineering. These claims are inconsistent with claim 14.

Claims 29-30 are indefinite because they depend from cancelled claim 1. Thus, it is unclear if they are intended to be part of non-elected Group I, or if the dependency is just wrong. For purposes of prior art, these claims will be treated as dependent from claim 14 (which is probably what was meant and a simple typo was made).

Claim 31 is indefinite because of the use of the definite article “the” at the beginning of the claim. As written, it is indefinite whether this claim was intended to be independent and the word “the” accidentally used in the place of “a” or if the claim was intended to be dependent upon an earlier claim, but the claim number was left out. For purposes of prior art, the claim will be treated as independent.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 15, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712).

Muddiman teaches a method of determining a genotype of a bioagent (see page 1546 and 1547, column 1, where a G to C change in the B. subtilis sequence was determined), comprising:

*(a) selecting at least one pair of oligonucleotide primers, wherein one member of said pair of primers hybridizes to a first conserved region of nucleic acid encoding a ribosomal RNA and the other member of said pair of primer hybridizes to a second conserved region of nucleic acid encoding ribosomal RNA wherein said first and second conserved regions flank a variable nucleic acid region which varies among bioagents* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches selection of conserved primers at page 3708, column 1, paragraph 2 with a variable region between the conserved primers),

*(b) amplifying nucleic acid from said bioagent with said pair of oligonucleotide primers to produce an amplification product* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches PCR amplification at page 3707, column 1, subheading "polymerase chain reaction"),

*(c) determining the molecular mass of said amplification product by mass spectrometry* (see page 1544, where the mass spectrometry methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches mass spectrometry at page 3707, column 2, subheading "Mass spectrometry"),

*(d) calculating the base composition of said amplification product from said molecular mass* (see table 1, where base composition was determined and see page 1547, column 1, where the first ranked mass was consistent with DNA sequencing results),

*(e) comparing said base composition to calculated or measured base compositions of amplification products of known bioagents produced by using said pair of oligonucleotide primers, thereby identifying the unknown bioagent at the species level* (see table 1, where Muddiman shows the expected base composition and the calculated base composition for each of *B. thuringiensis* and *B. subtilis*, thereby determining the species of each amplification product)

*(f) identifying a sub-species characteristic of said bioagent, thereby determining the genotype of said bioagent* (see page 1546, column 2 and page 1547, column 1, where a G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic).

With regard to claim 15, Muddiman teaches detection of a single nucleotide polymorphism, the G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic (see page 1546, column 2 and page 1547, column 1).

With regard to claim 29, Muddiman teaches ESI-TOF mass spectrometry (see page 1543, column 2).

With regard to claim 30, Muddiman teaches detection of bacteria (see table 1).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 17, 18, 31, 32, 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) in view of Nakao et al (J. Clin. Microbiol. (1997) 35(7):1651-1655).

Muddiman teaches a method of determining a genotype of a bioagent (see page 1546 and 1547, column 1, where a G to C change in the *B. subtilis* sequence was determined), comprising:

*(a) selecting at least one pair of oligonucleotide primers, wherein one member of said pair of primers hybridizes to a first conserved region of nucleic acid encoding a*

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*ribosomal RNA and the other member of said pair of primer hybridizes to a second conserved region of nucleic acid encoding ribosomal RNA wherein said first and second conserved regions flank a variable nucleic acid region which varies among bioagents* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches selection of conserved primers at page 3708, column 1, paragraph 2 with a variable region between the conserved primers),

*(b) amplifying nucleic acid from said bioagent with said pair of oligonucleotide primers to produce an amplification product* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches PCR amplification at page 3707, column 1, subheading “polymerase chain reaction”),

*(c) determining the molecular mass of said amplification product by mass spectrometry* (see page 1544, where the mass spectrometry methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches mass spectrometry at page 3707, column 2, subheading “Mass spectrometry”),

*(d) calculating the base composition of said amplification product from said molecular mass* (see table 1, where base composition was determined and see page 1547, column 1, where the first ranked mass was consistent with DNA sequencing results),

*(e) comparing said base composition to calculated or measured base compositions of amplification products of known bioagents produced by using said pair*



*of oligonucleotide primers, thereby identifying the unknown bioagent at the species level* (see table 1, where Muddiman shows the expected base composition and the calculated base composition for each of *B. thuringiensis* and *B. subtilis*, thereby determining the species of each amplification product)

*(f) identifying a sub-species characteristic of said bioagent, thereby determining the genotype of said bioagent* (see page 1546, column 2 and page 1547, column 1, where a G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic).

With regard to claims 15 and 32, Muddiman teaches detection of a single nucleotide polymorphism, the G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic (see page 1546, column 2 and page 1547, column 1).

With regard to claim 29, 37, Muddiman teaches ESI-TOF mass spectrometry (see page 1543, column 2).

With regard to claim 30, 38, Muddiman teaches detection of bacteria (see table 1).

Muddiman does not teach PCR amplification of genes other than the rRNA genes for detection, though Muddiman clearly intends the method to be generic in application (see page 1543, for example).

Nakao teaches amplification using a pair of primers drawn to a virulence gene, the diptheria toxin gene (see abstract).

With regard to claims 17, 18, 34 and 35, Nakao teaches PCR of the diptheria toxin gene (see page 1652, column 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Muddiman to detect the diptheria toxin gene of Nakao since Nakao states that the problem is a desire to "allow for more rapid identification of toxigenic *C. diptheriae* (see page 1651, column 1)" and Nakao addresses this problem by using a PCR based assay (see page 1651, column 1). However, the PCR assay is slowed by the need to use electrophoretic gel separation, and the assay does not precisely define the product. Muddiman solves these problems using the mass spectrometric approach as Muddiman notes "This approach uses accurate mass measurements and can be extended by the use of mass shifts induced by modified base PCR or postamplification modification, providing a rapid and accurate scheme by which to characterize PCR products of increasing size. This scheme should be particularly attractive for rapid confirmation of the base composition of PCR products (see page 1549, column 2)." An ordinary practitioner would have been motivated to use Mass spectrometric detection of Muddiman in the method of Nakao in order to expedite the analysis of the Diptheria toxin samples and permit more rapid patient treatment.

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9. Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muddiman et al (1997) 69:1543-1549) as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) in view of Franzen (U.S. 6,180,372).

Muddiman teaches a method of determining a genotype of a bioagent (see page 1546 and 1547, column 1, where a G to C change in the *B. subtilis* sequence was determined), comprising:

*(a) selecting at least one pair of oligonucleotide primers, wherein one member of said pair of primers hybridizes to a first conserved region of nucleic acid encoding a ribosomal RNA and the other member of said pair of primer hybridizes to a second conserved region of nucleic acid encoding ribosomal RNA wherein said first and second conserved regions flank a variable nucleic acid region which varies among bioagents* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches selection of conserved primers at page 3708, column 1, paragraph 2 with a variable region between the conserved primers),

*(b) amplifying nucleic acid from said bioagent with said pair of oligonucleotide primers to produce an amplification product* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches PCR amplification at page 3707, column 1, subheading "polymerase chain reaction"),

*(c) determining the molecular mass of said amplification product by mass spectrometry* (see page 1544, where the mass spectrometry methods are indicated as

described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches mass spectrometry at page 3707, column 2, subheading "Mass spectrometry"),

*(d) calculating the base composition of said amplification product from said molecular mass (see table 1, where base composition was determined and see page 1547, column 1, where the first ranked mass was consistent with DNA sequencing results),*

*(e) comparing said base composition to calculated or measured base compositions of amplification products of known bioagents produced by using said pair of oligonucleotide primers, thereby identifying the unknown bioagent at the species level (see table 1, where Muddiman shows the expected base composition and the calculated base composition for each of B. thuringiensis and B. subtilis, thereby determining the species of each amplification product)*

*(f) identifying a sub-species characteristic of said bioagent, thereby determining the genotype of said bioagent (see page 1546, column 2 and page 1547, column 1, where a G to C change was detected in the B. subtilis sequence relative to the prior art sequence, demonstrating the presence of a specific B. subtilis genotype and consequently a specific sub species characteristic).*

With regard to claims 15 and 32, Muddiman teaches detection of a single nucleotide polymorphism, the G to C change was detected in the B. subtilis sequence relative to the prior art sequence, demonstrating the presence of a specific B. subtilis genotype and consequently a specific sub species characteristic (see page 1546, column 2 and page 1547, column 1).

Muddiman does not teach PCR amplification of VNTR sequences, though Muddiman clearly intends the method to be generic in application (see page 1543, for example).

Franzen teaches amplification of VNTR sequences for bacterial detection (see column 3, lines 23-38). Franzen directly suggests that mass spectrometric measurements can be used for rapid detection (see column 3, lines 40-45).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Muddiman to detect the VNTR sequences of Franzen since Franzen discusses VNTR analysis and relates this to the identification of infectious organisms (see column 3, lines 35-38) and since Franzen expressly suggests mass spectrometric methods of analysis (see column 3, lines 40-45). Muddiman teaches the advantages of the base measurement method noting "This approach uses accurate mass measurements and can be extended by the use of mass shifts induced by modified base PCR or postamplification modification, providing a rapid and accurate scheme by which to characterize PCR products of increasing size. This scheme should be particularly attractive for rapid confirmation of the base composition of PCR products (see page 1549, column 2)." An ordinary practitioner would have been motivated to use Mass spectrometric detection of Muddiman in the method of Franzen in order to

expedite the analysis of the VNTR samples and permit "identification of infectious organisms (see column 3, line 36 of Franzen)."

10. Claims 17-19, 31, 32, and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muddiman et al (1997) 69:1543-1549 as evidenced by Muddiman et al (Anal. Chem. (1996) 68:3705-3712) in view of Nishikawa (FEMS Microbiol. Letters (1999) 178:13-18).

Muddiman teaches a method of determining a genotype of a bioagent (see page 1546 and 1547, column 1, where a G to C change in the *B. subtilis* sequence was determined), comprising:

*(a) selecting at least one pair of oligonucleotide primers, wherein one member of said pair of primers hybridizes to a first conserved region of nucleic acid encoding a ribosomal RNA and the other member of said pair of primer hybridizes to a second conserved region of nucleic acid encoding ribosomal RNA wherein said first and second conserved regions flank a variable nucleic acid region which varies among bioagents* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches selection of conserved primers at page 3708, column 1, paragraph 2 with a variable region between the conserved primers),

*(b) amplifying nucleic acid from said bioagent with said pair of oligonucleotide primers to produce an amplification product* (see page 1544, where the PCR methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712),

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which teaches PCR amplification at page 3707, column 1, subheading “polymerase chain reaction”),

*(c) determining the molecular mass of said amplification product by mass spectrometry* (see page 1544, where the mass spectrometry methods are indicated as described in Muddiman et al (Anal. Chem. (1996) 68:3705-3712), which teaches mass spectrometry at page 3707, column 2, subheading “Mass spectrometry”),

*(d) calculating the base composition of said amplification product from said molecular mass* (see table 1, where base composition was determined and see page 1547, column 1, where the first ranked mass was consistent with DNA sequencing results),

*(e) comparing said base composition to calculated or measured base compositions of amplification products of known bioagents produced by using said pair of oligonucleotide primers, thereby identifying the unknown bioagent at the species level* (see table 1, where Muddiman shows the expected base composition and the calculated base composition for each of *B. thuringiensis* and *B. subtilis*, thereby determining the species of each amplification product)

*(f) identifying a sub-species characteristic of said bioagent, thereby determining the genotype of said bioagent* (see page 1546, column 2 and page 1547, column 1, where a G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic).

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With regard to claims 15 and 32, Muddiman teaches detection of a single nucleotide polymorphism, the G to C change was detected in the *B. subtilis* sequence relative to the prior art sequence, demonstrating the presence of a specific *B. subtilis* genotype and consequently a specific sub species characteristic (see page 1546, column 2 and page 1547, column 1).

With regard to claim 29, 37, Muddiman teaches ESI-TOF mass spectrometry (see page 1543, column 2).

With regard to claim 30, 38, Muddiman teaches detection of bacteria (see table 1).

Muddiman does not teach PCR amplification of genes other than the rRNA genes for detection, though Muddiman clearly intends the method to be generic in application (see page 1543, for example).

Nishikawa teaches PCR amplification of a recombinant shiga toxin gene (see figure 2).

With regard to claims 17, 18, 34 and 35, Nishikawa teaches PCR of the shiga toxin gene (see figure 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Muddiman to detect the recombinant shiga toxin gene of Nishikawa since Muddiman notes "This approach uses accurate mass measurements and can be extended by the use of mass shifts induced by modified



base PCR or postamplification modification, providing a rapid and accurate scheme by which to characterize PCR products of increasing size. This scheme should be particularly attractive for rapid confirmation of the base composition of PCR products (see page 1549, column 2)." An ordinary practitioner would have been motivated to use Mass spectrometric detection of Muddiman in the method of Nishikawa in order to expedite the analysis of the shiga toxin samples and permit more rapid PCR detection.

***Double Patenting***

11. Claims 14-19 and 29-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59,60,62,63,66,69-76 and 79-94 of copending Application No. 10/156,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims represent a species of the current claims in which specific numbers of species are in the database and where specific mass is determined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 14-19 and 29-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 14, 17, 28-44 of copending Application No. 10/660,996. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims represent a species of the current claims in which subtypes are not necessarily detected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

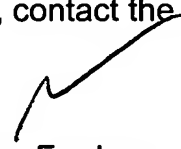
### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

5/4/06